

Receipt



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Washington, D.C. 20231

December 29, 2000

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TECH CENTER 1600/2900

Re: Request for Corrected Filing Receipt  
Application No.: 09/677,374  
Filing Date: September 15, 2000  
Our Ref. No.: 1115-005/ddh

Dear Sir or Madam:

The application noted above is a non-provisional application that claims priority from prior provisional application no. 60/154,437. A copy of the cover sheet filed with the present application and the declaration (unsigned) are enclosed. The Filing Receipt does not include the proper data regarding the claim of priority. A copy of the Filing Receipt with the changes noted thereon is also enclosed.

Please issue a corrected filing receipt for this application. If you have any questions or need further information, please contact the undersigned by telephone.

Sincerely,

Douglas D. Hancock

enclosures

cc: Ted Urbanek

Express Mail Lab EL304655126US  
DATE OF DEPOSIT: September 15, 2000

Attorney's Ref. No. 1115-005/dsh



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box PATENT APPLICATION  
ASSISTANT COMMISSIONER FOR PATENTS  
Washington, D.C. 20231

EL304655126US

Transmitted herewith for filing is the patent application of:  
Inventor: Michael A. Kuzyk et al.

For: VACCINES AND AGENTS FOR INDUCING IMMUNITY IN FISH AGAINST RICKETTSIAL  
DISEASES, AND ASSOCIATED PREVENTATIVE THERAPY

Enclosed are:

- [X] Patent application with 21 pages of specification, 3 pages of claims, an abstract, and 11 sheets of drawings.
- [X] Combined Declaration and Power of Attorney (unsigned)
- [X] **This is a non-provisional application claiming priority from prior application no 60/154,437**

CLAIMS AS FILED					
For	Number Filed		Number Extra	Rate	Basic Fee
Total claims	32	-20	12	=	0
Independent Claims	13	-3	10	=	0
TOTAL FILING FEE					

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MAP. 2/3 2001

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4370 NE Halsey Street  
Portland, Oregon 97213  
Telephone: (503) 249-7066  
cc: Robert Barrigar

Respectfully submitted,

Douglas D. Hancock  
Registration No. 35,889

**Vaccines and Agents for Inducing Immunity in Fish Against Rickettsial Diseases, And Associated Preventative Therapy**



**Reference to Related Applications**

This application claims the benefit of U.S. Provisional Application No. 60/154,437, filed September 17, 1999.

**Field of the Invention**

This invention relates generally to the field of obligate intracellular bacteria, and in particular to agents of rickettsia type diseases, specifically *Piscirickettsia salmonis* in aquatic poikilotherms. The invention also encompasses isolated genes encoding outer surface antigens of *P. salmonis* and the diagnostic and therapeutic use (including in particular the preparation of a recombinant vaccine to prevent or reduce the incidence of infection by *P. salmonis* and other rickettsial diseases) of such antigens or their homologues.

In particular aspects, this invention relates to the use of the 17 kDa outer surface lipoprotein (OspA) of *Piscirickettsia salmonis*, or its homologues, as the basis of, or part thereof, a recombinant vaccine for salmonid rickettsial septicaemia and other rickettsial diseases. This invention also relates to the augmentation of protective immunity by the inclusion of promiscuous T lymphocyte epitopes (TCE's) in fusion protein constructs in salmonids. This invention also relates to the use of bacterial protein inclusion bodies as a source of the protective immunogen.

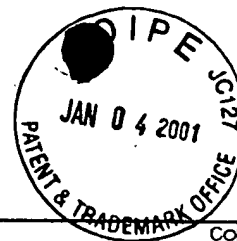
**Background of the Invention**

The order *Rickettsiales* historically encompassed any intracellular bacterium and taxonomy was based on only a few phenotypic characteristics (Drancourt and Raoult, 1994). More recently, 16S rRNA sequence similarity studies have helped to better define the taxonomy of the order *Rickettsiales* (Drancourt and Raoult, 1994). Rickettsiae cause a variety of medically significant diseases in humans including typhus fever, Rocky Mountain spotted fever, and boutonneuse fever (Pang and Winkler, 1994; Vishwanath, *et al.*, 1990). Rickettsiae are also agriculturally significant, and are the aetiological agents of a variety of veterinary diseases (Rikihisa, 1991).

The past decade has been a renaissance in the identification of rickettsial and rickettsial-like infections as the aetiological agents of poorly understood diseases and as emerging pathogens (Anderson, 1997; Azad, *et al.*, 1997; Davis, *et al.*, 1998; Fryer and Mauel, 1997; Stenos, *et al.*, 1998). Inherent difficulties are associated with rickettsials: it is very difficult to grow large quantities of rickettsiae; rickettsiae have very slow growth rates; and rickettsiae are difficult to separate from host cell material (Higgins, *et al.*, 1998). Although rickettsiae lack a characterized genetic system for genetic manipulation (Mallavia, 1991), the advent of recombinant DNA technology has revolutionized rickettsial research. Characterization of rickettsial pathogenesis and functional analysis of rickettsial antigens has largely relied upon antibody inactivation studies (Li and Walker,



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APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/677,374	09/15/2000	1642	0	1115-005/ddh	11	32	13

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## FILING RECEIPT



\*OC000000005618232\*

Date Mailed: 12/13/2000

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Michael A. Kuzyk, Victoria, CANADA;  
Jan Burian, Victoria, CANADA;  
William W. Kay, Victoria, CANADA;  
Julian C. Thornton, Victoria, CANADA;

## Continuing Data as Claimed by Applicant

*Provisional Application No 60/154,437*

## Foreign Applications

If Required, Foreign Filing License Granted 12/13/2000

## Title

Vaccines and agents for inducing immunity in fish against rickettsial diseases, and associated preventative therapy

## Preliminary Class

424

Data entry by : MASON, JAMES

Team : OIPE

Date: 12/13/2000



*xc -> Ted Urbank*

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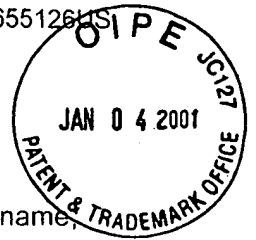
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Bib Data Sheet

<b>SERIAL NUMBER</b> 09/677,374	<b>FILING DATE</b> 09/15/2000 <b>RULE</b> -	<b>CLASS</b> 424	<b>GROUP ART UNIT</b> 1642	<b>ATTORNEY DOCKET NO.</b> 1115-005/ddh
<b>APPLICANTS</b> Michael A. Kuzyk, Victoria, CANADA; Jan Burian, Victoria, CANADA; William W. Kay, Victoria, CANADA; Julian C. Thornton, Victoria, CANADA;				
<b>** CONTINUING DATA *****</b> THIS APPLN CLAIMS BENEFIT OF 60/154,437 09/17/1999				
<b>** FOREIGN APPLICATIONS *****</b>				
<b>IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 12/13/2000</b>				
Foreign Priority claimed <input type="checkbox"/> yes <input type="checkbox"/> no 35 USC 119 (a-d) conditions <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> Met after met Allowance Verified and Acknowledged <u>Examiner's Signature</u> <u>Initials</u>		<b>STATE OR COUNTRY</b> CANADA	<b>SHEETS DRAWING</b> 11	<b>TOTAL CLAIMS</b> 32
				<b>INDEPENDENT CLAIMS</b> 13
<b>ADDRESS</b> Ipsolon llp 4370 NE Halsey Street Portland ,OR 97213				
<b>TITLE</b> Vaccines and agents for inducing immunity in fish against rickettsial diseases, and associated preventative therapy				
<b>FILING FEE RECEIVED</b> 0	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		<input type="checkbox"/> All Fees <input type="checkbox"/> 1.16 Fees ( Filing ) <input type="checkbox"/> 1.17 Fees ( Processing Ext. of time ) <input type="checkbox"/> 1.18 Fees ( Issue ) <input type="checkbox"/> Other _____ <input type="checkbox"/> Credit	

COMBINED DECLARATION AND POWER OF ATTORNEY  
FOR PATENT APPLICATION



As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled VACCINES AND AGENTS FOR INDUCING IMMUNITY IN FISH AGAINST RICKETTSIAL DISEASES, AND ASSOCIATED PREVENTATIVE THERAPY, the specification of which

- ☒ is attached hereto.  
☐ was filed on \_\_\_\_\_ as Application No. \_\_\_\_\_.  
☐ was described and claimed in PCT International Application No. \_\_\_\_\_, filed on \_\_\_\_\_, and as amended under PCT Article 19 on \_\_\_\_\_ (if applicable).  
☐ and was amended on \_\_\_\_\_ (if applicable).  
☐ with amendments through \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56. If this is a continuation-in-part application filed under the conditions specified in 35 U.S.C. § 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, I further acknowledge the duty to disclose material information as defined in 37 CFR § 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT International application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
			<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

60/154,437

(Application No.)

September 17, 1999

(Filing Date)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) or § 365(c) of any PCT International application(s) designating the United States,